SECTION II. SUMMARY AND CERTIFICATION

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. Device Name

Proprietary Name	Glidesheath
Classification Name	Introducer, Catheter
Common Name	Introducer Sheath

B. Intended Use

The Glidesheath is used to facilitate placing a catheter through the skin into a vein or artery. The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery. The RADIFOCUS Obturator is also an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling sheath while it remains in place within the vein or artery after removal of a catheter.

Note: This is the same intended use as the RADIFOCUS® Introducer II Kit , K954234.

C. Device Description

The Glidesheath is comprised of an introducer sheath and a dilator.

The Glidesheath is used to facilitate placement of a catheter through the skin into a vein or artery. A Mini Guide Wire (with Inserter) may be included with the Glidesheath. The Inserter does not contact blood and is used strictly for guiding the Guide Wire into a cannula or Introducer.

The Mini Guide Wire is inserted through a cannula placed in the patient's blood vessel. The Glidesheath is then inserted over the Mini Guide Wire and into the blood vessel. The Mini Guide Wire is then withdrawn from the vessel. The Dilator maintains the integrity of the Sheath and dilates the blood vessel while the Glidesheath is being placed into the vessel. The Dilator can be removed and an appropriate catheter can then be inserted. The RADIFOCUS Obturator is an accessory device which creates an occlusion when inserted into the Sheath. The

Obturator also provides support to the indwelling Sheath after the catheter is removed.

The Sheath, Dilator and Obturator contain bismuth, making these devices visible under fluoroscopy.

D. *Principle Of Operation / Technology*

The Glidesheath and its accessories are operated manually or by a manual process.

E. *Design / Materials*

Differences in materials between the Glidesheath and the RADIFOCUS® Introducer II Kit, K954234 raise no new issues of safety and effectiveness.

F. *Specifications*

Part	**Glidesheath**	**RADIFOCUS® Introducer II, K954234**
Introducer Sheath Size Length	 5 & 6 French 10-25 cm	 4 – 11 French 5 – 110 cm
Dilator Length	 15.5 – 30.5 cm	 6 – 110 cm
Guide Wire OD	0.021" – 0.038"	0.021" – 0.038"

G. *Performance*

The Glidesheath is comprised of an introducer sheath and a dilator. Only the introducer sheath was modified. The dilator was not modified.

The following verification tests were performed to demonstrate the substantial equivalence of the modified device (Glidesheath) to the unmodified device (RADIFOCUS® Introducer II).

- Leakage/clogging
- Tensile strength of connections
- Separation force of dilator and sheath
- Internal sliding resistance
- External sliding resistance
- Penetration force

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new issues of safety and effectiveness.

Therefore the performance of the Glidesheath is substantially equivalent to the performance of the RADIFOCUS® Introducer II, cleared under K954234.

H. *Additional Safety Information*

Manufacturing controls include visual, functional, dimensional and sterility tests.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".

The introducer sheath is classified as Externally Communicating Devices, Circulating Blood, Prolonged Contact (24 hrs to 30 days). Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance with ANSI / AAMI / ISO 11135-1994, *Medical Devices – Validation and routine control of ethylene oxide sterilization* and EN 550. The device is sterilized to a SAL of 10^{-6}.

I. Substantial Equivalence

The Glidesheath is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the RADIFOCUS® Introducer II, cleared under K954234. Differences between the two devices do not raise any significant issues of safety or effectiveness.

J. Submitter Information

Prepared By:	Mr. Mark Unterreiner Regulatory Affairs Specialist
Prepared For:	Terumo Medical Corporation 125 Blue Ball Road Elkton, MD 21921 Phone: (410) 392-7213 Fax: (410) 398-6079 Email: mark.unterreiner@terumomedical.com
Date Prepared:	November 21, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2003

Mr. Mark Unterreiner
Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K033681
Trade Name: Glidesheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: II
Product Code: 74 DYB
Dated: November 21, 2003
Received: November 23, 2003

Dear Mr. Unterreiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Note: This is the same intended use as the predicate device, K954234

510(k) Number (if known): K033681

Device Name: Glidesheath

Indications For Use:

The Glidesheath is used to facilitate placing a catheter through the skin into a vein or artery. The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery. The RADIFOCUS Obturator is also an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling sheath while it remains in place within the vein or artery after removal of a catheter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

12/11/03
(Division Sign-off)
Division of Cardiovascular Devices

510(K) Number K033681 (SM. K)